IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

TONYA EDWARDS, et al.,

Plaintiffs,

v. CIVIL ACTION NO. 2:12-CV-09972

ETHICON, INC., et al.,

Defendants.

MEMORANDUM OPINION & ORDER

Pending before the court are Defendants' Motion for Partial Summary Judgment [Docket 83], Defendants' Motion for Partial Summary Judgment Based on Preemption of Certain Claims [Docket 87], and Defendants' Motion for Partial Summary Judgment on Punitive Damages [Docket 93]. For the reasons stated below, Defendants' Motion for Partial Summary Judgment [Docket 83] is **GRANTED as unopposed**, Defendants' Motion for Partial Summary Judgment Based on Preemption of Certain Claims [Docket 87] is **DENIED**, and Defendants' Motion for Partial Summary Judgment on Punitive Damages [Docket 93] is **GRANTED**.

I. Background

This case is one of more than 60,000 that have been assigned to me by the Judicial Panel on Multidistrict Litigation in seven MDLs involving pelvic mesh products. Approximately 19,000 of these cases reside in the *In re Ethicon, Inc.* MDL, MDL No. 2327.

The device at issue in this case is the Gynecare TVT Obturator ("TVT-O"), manufactured by the defendants, Ethicon, Inc. and Johnson & Johnson, Inc. (collectively, "Ethicon"). The

TVT-O is a medical device used to place a mesh tape, or sling, under the urethra to provide support to the urethra to treat stress urinary incontinence. (Mem. in Supp. of Mot. for Partial Summ. J. [Docket 162], at 1). The plaintiff in this case, Ms. Edwards, was implanted with a TVT-O. The defendants have filed three motions for summary judgment.

II. Legal Standards

A. Summary Judgment

To obtain summary judgment, the moving party must show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). In considering a motion for summary judgment, the court will not "weigh the evidence and determine the truth of the matter." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). Instead, the court will draw any permissible inference from the underlying facts in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 587-88 (1986).

Although the court will view all underlying facts and inferences in the light most favorable to the nonmoving party, the nonmoving party nonetheless must offer some "concrete evidence from which a reasonable juror could return a verdict in his [or her] favor[.]" *Anderson*, 477 U.S. at 256. Summary judgment is appropriate when the nonmoving party has the burden of proof on an essential element of his or her case and does not make, after adequate time for discovery, a showing sufficient to establish that element. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). The nonmoving party must satisfy this burden of proof by offering more than a mere "scintilla of evidence" in support of his or her position. *Anderson*, 477 U.S. at 252. Likewise, conclusory allegations or unsupported speculation, without more, are insufficient to preclude the

granting of a summary judgment motion. *See Felty v. Graves Humphreys Co.*, 818 F.2d 1126, 1128 (4th Cir. 1987); *Ross v. Comm'ns Satellite Corp.*, 759 F.2d 355, 365 (4th Cir. 1985), *abrogated on other grounds, Price Waterhouse v. Hopkins*, 490 U.S. 228 (1989).

B. Preemption

Federal preemption originates from the Constitution's Supremacy Clause. *See* U.S. Const. art. VI, cl. 2.[1] In addressing a preemption issue, the court's first task is to determine whether Congress intended to preempt. *See Cal. Fed. Savings & Loan Ass'n v. Guerra*, 479 U.S. 272, 280-81 (1978). Intent to preempt can manifest itself in three forms: field preemption, express preemption, and conflict preemption. *See H&R Block E. Enters. v. Raskin*, 591 F.3d 718, 722 (4th Cir. 2010). Field preemption occurs when the "federal scheme of regulation of a defined field is so pervasive that Congress must have intended to leave no room for the states to supplement it[.]" *City of Charleston, S.C. v. A Fisherman's Best, Inc.*, 310 F.3d 155, 169 (4th Cir. 2002). Express preemption arises when "Congress expressly declares its intent to preempt state law." *Pinney v. Nokia, Inc.*, 402 F.3d 430, 453 (4th Cir. 2005). Finally, conflict preemption occurs when "state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hillsborough Cnty., Fla. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 713 (1985) (internal quotation omitted). Conflict preemption can also arise when "compliance with both federal and state regulations is a physical impossibility[.]" *Id.* (internal quotation omitted).

Once Congress's intent to preempt is determined, the focus turns to the scope of that preemption. *See Duvall v. Bristol-Myers-Squibb Co.*, 103 F.3d 324, 328 (4th Cir. 1996). Two presumptions guide this inquiry. *See id.* First, "'the purpose of Congress is the ultimate

[1] "This Constitution, and the Laws of the United States which shall be made in Pursuance thereof . . . shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2.

touchstone' in every pre-emption case." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (quoting *Retail Clerks v. Schermerhorn*, 375 U.S. 96, 103 (1963)). Second, a court starts "with the basic assumption that Congress did not intend to displace state law." *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981). "This presumption is strongest when Congress legislates 'in a field which the States have traditionally occupied.'" *S. Blasting Servs., Inc. v. Wilkes Cnty., N.C.*, 288 F.3d 584, 590 (4th Cir. 2002) (quoting *Lohr*, 518 U.S. at 485).

C. Choice of Law

The parties agree that Georgia's choice-of-law rules apply in this case. Georgia follows the doctrine of lex loci delicti, which dictates that "a tort action is governed by the substantive law of the state where the tort was committed." *Dowis v. Mud Slingers, Inc.*, 621 S.E.2d 413, 414 (Ga. 2005). "The place where the tort was committed, or, 'the locus delicti, is the place where the injury sustained was suffered rather than the place where the act was committed, or, as it is sometimes more generally put, it is the place where the last event necessary to make an actor liable for an alleged tort takes place.'" *Bullard v. MRA Holding*, 740 S.E.2d 622, 625 (Ga. 2013) (quoting *Risdon Enter., Inc. v. Colemill Enter., Inc.*, 324 S.E.2d 738, 740 (Ga. 1984)). Ms. Edwards's alleged injury occurred in Georgia; therefore, Georgia law governs the plaintiffs' claims.

III. Analysis

A. Defendants' Motion for Partial Summary Judgment on Plaintiffs' Claims of Manufacturing Defect, Breach of Express Warranty, Breach of Implied Warranty, Georgia Consumer Protection Statutes, and Unjust Enrichment

Ethicon moved for summary judgment on the plaintiffs' claims for manufacturing defect, breach of express warranty, breach of implied warranty, Georgia's consumer protection statutes,

and unjust enrichment. The plaintiffs did not respond to or otherwise oppose this motion. Therefore, Ethicon's motion is **GRANTED as unopposed**.

B. Defendants' Motion for Partial Summary Judgment Based on Preemption of Certain Claims

Ethicon argues that the plaintiffs' claims should be preempted to the extent that any claim contends "that PROLENE* in mesh degrades and that degradation leads to other consequences, such as infection." (Mot. for Partial Summ. J. Based on Preemption of Certain Claims ("Preemption Mot.") [Docket 87], at 2). Ethicon bases this argument on the fact that the Prolene suture, which they argue is a component part of the TVT-O, went through the FDA's rigorous premarket approval process, rather than the less stringent 510(k) clearance process. The Prolene suture is a different medical device and, like the mesh contained in the TVT-O, is made of polypropylene. This court examined that exact issue in *Lewis v. Johnson & Johnson* and found that the plaintiffs' claims were not preempted. *See* --- F. Supp. 2d ---, No. 2:12-cv-04301, 2014 U.S. Dist. LEXIS 4985, at *32 (S.D. W. Va. Jan. 15, 2014); *see also id.* at *4-5 for a discussion of the differences between 510(k) clearance and premarket approval. As noted in *Lewis*, the Supreme Court has determined that claims related to devices approved through the FDA's premarket approval process are preempted while claims related to medical devices cleared through the FDA's 510(k) clearance process are not. *See id.* at *18-19; *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 322-23 (2008); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 501-02 (1996).

Ethicon attempts to distinguish the instant case from *Lewis* and argues that the court has not yet addressed the following issues:

> (1) the fact that the FDA-approval of PROLENE* polypropylene for use in the body is the "status quo" for that material and, whatever the Court's views of the safety and efficacy considerations of the 510(k) process, the approval of that

> component is not stripped away because the device as a whole was later cleared through the 510(k) process; (2) that Plaintiffs' claims regarding degradation and resulting inflammation and infection stem from the PROLENE* polypropylene-based filaments, not the other parts of the kit; and (3) evidence that the quantity of PROLENE* used does not have any effect on whether the PROLENE* degrades when placed in the human body.

(Preemption Mot. [Docket 87], at 1-2). Ethicon's arguments are without merit. As I explained in *Lewis*,

> Ethicon's argument ignores the fact that the Prolene suture and the TVT are two entirely different medical devices that went through different FDA processes. Although Ethicon represents that the products are primarily composed of the same material, it does not automatically follow that the material is safe in both devices. The Prolene suture is a nonabsorbable surgical suture; the TVT is a form of transvaginal mesh. The Prolene suture consists of a single filament of polypropylene; the TVT is a mesh woven from knitted Prolene filaments. The average Prolene suture is a few inches long; the TVT measures one-half inches by sixteen inches, and contains many times the amount of polypropylene material. The Prolene suture is not intended to adhere to human tissue; the TVT is designed to adhere to human tissue. The Prolene suture is designed to be easily pulled out of the body; the TVT cannot be removed without invasive surgery. . . .
>
> The FDA's approval of the Prolene suture necessarily related to its use as a suture; it did not categorically approve Prolene filament for use in medical devices. When the FDA approved the Prolene suture, it stated that it had concluded the Prolene suture was "safe and effective *for use as recommended in the submitted labeling*." The FDA did not examine whether that same material was safe when woven together to create a transvaginal mesh product. Ethicon would like the court to determine that because the FDA found polypropylene is safe to use as a suture, it is automatically safe to use in transvaginal mesh. Although purportedly constructed of the same material, it is a different product, used in a different manner, for a different purpose. The plaintiffs have presented evidence demonstrating the difference in risk profiles between the Prolene suture and TVT, and evidence that the process of weaving the filaments creates different surface characteristics in the mesh. If a specific type of metal were approved for use in a bone screw via the premarket approval process, it would not follow that that same type of metal was safe in all medical devices, no matter what their function in the human body. The same is true for Prolene filament. It does not follow that the same Prolene filament that is safe for use as a suture is automatically safe for use in transvaginal mesh.

2014 U.S. Dist. LEXIS 4985, at *24-25 (internal citations omitted).

Additionally,

"[p]ersuasive authority from other district courts . . . indicates that the preemption analysis is not applied differently to the component parts of a medical device and the medical device itself[.]" *Gavin v. Medtronic, Inc.*, CIV.A. 12-0851, 2013 WL 3791612, at *11 (E.D. La. July 19, 2013). Interestingly, the shoe is normally on the other foot—the defendant is arguing that a cause of action is preempted because a device underwent premarket approval, while the plaintiff is arguing there is no preemption because a component part of the device underwent 510(k) clearance. Courts addressing this issue have determined that a device should not be broken into its component parts in order to apply a preemption analysis . . . . The same reasoning used in those cases is applicable here: analyzing the component parts of a device separately from the device itself simply does not make sense.

"To require that a distinction be drawn between the approval process of the individual components of a system and the system itself, would, it seems, add a level of complication to the medical device approval process not anticipated by Congress, the FDA, or medical device manufacturers." *Lewkut*, 724 F. Supp. 2d at 656. "It makes no sense—indeed, it would probably be impossible—to pick apart the components of a medical device and apply different preemption analyses to different components." *Riley*, 625 F. Supp. 2d at 780. Determining preemption based upon the component parts of a device, rather than the device as a whole, would create a legal quagmire whereby tort claims against one part of a device are preempted while tort claims against another part of a device are not. Indeed, this is exactly what Ethicon would like the court to declare—as Ethicon noted, its "motion addresses only the use of PROLENE filaments and does not address other alleged defects, such as mesh pore size." (Defs.' Mot. for Summ. J. [Docket 128], at 1).

Analyzing each component of a medical device separately to determine whether claims are preempted would create a doctrine that forces courts to dissect every medical device. In that world, a different preemption analysis would apply to each part of the device, rather than the device as a whole. *See Phillips*, 2010 WL 2270683, at *5 n.4 (noting the "serious practical difficulties" with separating the device from its component parts to determine preemption). Particularly in complex litigation such as this, bright line rules are important to create clarity for all parties involved. The doctrine Ethicon asks this court to accept would only serve to create chaos in a field that is already difficult to navigate. Each involved party should be able to determine whether tort claims regarding a medical device are preempted based upon the review process the device actually went through. If the TVT had gone through the premarket approval process while the polypropylene filament had gone through the 510(k) process, I cannot imagine that Ethicon would think the component parts of a device should be analyzed separately from the device itself. As discussed above, Ethicon itself has recognized the importance of viewing the TVT as a whole, rather than just its component parts. Just as "a device receiving

> premarket approval cannot be separated into its component parts to avoid application of express preemption," *Gross*, 858 F. Supp. 2d at 487, a device receiving 510(k) approval cannot be separated into its component parts to create express preemption.

Id. at *27-32. None of Ethicon's arguments demonstrate that I should deviate from this reasoning. Although Ethicon may have rephrased some of its arguments and has submitted an additional declaration from an Ethicon employee, the legal reasoning here is the same as in *Lewis*.

Ethicon also argues that I should reconsider my ruling in *Lewis* based on the reasoning in two other cases: *Bertini v. Smith & Nephew, Inc.*, No. 13 Civ. 79, 2014 U.S. Dist. LEXIS 35837 (E.D.N.Y. Mar. 17, 2014) and *Simon v. Smith & Nephew, Inc.*, No. 13 CIV. 1909 PAE, 2013 WL 6244525 (S.D.N.Y. Dec. 3, 2013). These cases concern the same allegedly defective hip replacement system, the R3 Acetabular System, developed by Smith & Nephew. *See Bertini*, 2014 U.S. Dist. LEXIS 35837, at *2; *Simon*, 2013 WL 6244525, at *4. The R3 System "is a hip implant system used in total hip replacement procedures." *Bertini*, 2014 U.S. Dist. LEXIS 35837, at *2. "The R3 System is made up of the Acetabular Cup (shell) . . . and one of several possible liners." *Id.* The purpose of the liner is "to prevent the loosening of the hip components, which is a defect in total hip replacement systems that often results in pain and a decrease in the hip implant's stability." *Id.* The R3 System received 510(k) clearance from the FDA. *Id.* at *2-3. Later, Smith & Nephew developed a new hip replacement system, the Birmingham Hip Resurfacing ("BHR") System. *Id.* at 3. The BHR System was approved through the premarket approval process. *Id.* Thereafter, the FDA granted supplemental premarket approval to the BHR System using the R3 acetabular metal hip liner. *Id.* at 3-4. Essentially, the premarket approval of the BHR System was amended to include one of the same components as the R3 System—the R3 acetabular metal hip liner. *See id.* Importantly, in both *Bertini* and *Simon*, the plaintiff was implanted with an R3

System (which received 510(k) clearance rather than premarket approval), not the BHR System. *See Bertini*, 2014 U.S. Dist. LEXIS 35837, at *12; *Simon*, 2013 WL 6244525, at *4.

In *Simon*, the plaintiff argued that the R3 System was defectively designed. *See* 2013 WL 6244525, at *4. The plaintiff argued that the design defect claims were not preempted because the R3 system was not approved through the premarket approval process. *See id.* at *4. The defendant argued that each of the plaintiff's claims "challenge[d] the safety and effectiveness of the optional metal liner; and the R3 metal liner was indeed [premarket]-approved." (*Id.*). The court's actual holding in *Simon* was that the plaintiff's Amended Complaint failed to state a claim for strict liability, negligence, and breach of implied warranty. *See id.* at *6, 7, 8. However, the court also found that even if the complaint had stated claims, those claims would have been preempted. *See id.* In relevant part, the court stated:

> [E]ven if the Amended Complaint were fairly read to assert a claim of design defect based solely on the optional metal liner, any such claim would be preempted. That is because the optional metal liner received supplemental [premarket] approval in conjunction with the BHR System. As noted, design defect claims regarding a [premarket]-approved device are squarely preempted by the [Medical Device Amendments to the Food, Drug and Cosmetic Act]. Such preemption extends to a component of a [premarket]-approved device.

Id. at *7. To support this proposition, the court cited to *Lewkut v. Stryker Corp.*, 724 F. Supp. 2d 648, 656 (S.D. Tex. 2010), which stated: "To require that a distinction be drawn between the approval process of the individual components of a system and the system itself, would, it seems, add a level of complication to the medical device approval process not anticipated by Congress, the FDA, or medical device manufacturers." *Id.* It also cited to *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 780 (D. Minn. 2009), for the proposition that "separating components of [premarket]-approved device to apply different preemption analysis 'makes no sense.'" *Id.*

I respectfully disagree with the *Simon* court's analysis. First, neither *Lewkut* nor *Riley* held that premarket approval of a component part of a device meant that all claims against a 510(k) cleared device were preempted. Notably, *Lewkut* dealt with a device that was, as a whole, approved through the premarket approval process. *See* 724 F. Supp. 2d at 652. That device contained a component that, prior to the device's premarket approval, was cleared through the 510(k) process. *See id.* The court in *Lewkut* found the fact that the component part "was previously approved through only the § 510(k) process, and was commercially available when" the medical device received premarket approval did "not change the fact that it was later subject to the more rigorous scrutiny of the [premarket approval] process as a component of" the full medical device. *Id.* at 657. The court ultimately held that because the entire device had gone through the premarket approval process, the plaintiff's claims were preempted. *See id.* at 658. The *Simon* court's reliance on *Lewkut* is misplaced; in *Lewkut*, the entire device had received premarket approval.

The other case relied upon by the *Simon* court, *Riley*, also dealt with a device that had received premarket approval. *See* 625 F. Supp. 2d at 774-75. The plaintiff there argued that because the approved device was coated with a drug, the preemption analysis of *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 322-23 (2008), should not apply. *See id.* at 779. The *Riley* court noted that the device at issue was "not merely a drug or merely a drug-delivery system; it [was] instead a compound of mechanical and chemical parts that work together as a single medical device. In approving the [device], the FDA exercised its authority to regulate medical devices, not its authority to regulate drugs." *Id.* It also noted that the plaintiff's claims were "manifestly claims against the device as a whole." *Id.* at 780. The court found that because the FDA had approved and

regulated the completed product as a medical device, the court should apply the express preemption analysis set forth in *Riegel*. *See id.*

As the above discussion reveals, the *Simon* court's reliance on *Lewkut* and *Riley* as support for applying total preemption to a medical device that only received 510(k) clearance was misguided. Both *Lewkut* and *Riley* dealt with whether product liability claims regarding a device that received premarket approval were preempted; the Supreme Court has been clear that they are. *See Riegel*, 552 U.S. at 330 ("State requirements are pre-empted under the [Medical Device Amendments] . . . to the extent that they are 'different from, or in addition to' the requirements imposed by federal law."). The Supreme Court has been equally clear that product liability claims regarding a device that received 510(k) clearance are *not* preempted. *See Medtronic v. Lohr*, 518 U.S. 470, 494 (1996). The courts in *Lewkut* and *Riley* followed the Supreme Court precedent that claims against a device that receives premarket approval are generally preempted.[2] The court in *Simon*, on the other hand, deviated from Supreme Court precedent which found that claims against a device receiving 510(k) approval are *not* preempted. Read in their entirety, the cases cited in *Simon* do not suggest that premarket approval of a component part of a device means that claims against the entire device should be preempted.

The *Bertini* court's analysis likewise seems to confuse the preemption analysis. The court repeatedly notes that preemption applies to a device as a whole rather than component parts but then finds that the plaintiffs' claims are preempted because of the premarket approval of a component part, ignoring the status of the device as a whole:

[2] Claims against a device that received premarket approval are not preempted to the extent that they assert that the device manufacturer failed to obey FDA requirements. *See Riegel*, 552 U.S. at 330 (stating that the Federal Food, Drug and Cosmetic Act "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations"). However, this exception is irrelevant to the instant case.

> While the R3 metal liner is just one part of the hip replacement system, it is the main focus of plaintiffs' Complaint. Plaintiff[]s attribute Mr. Bertini's injuries to two separate but interrelated defects: "the loosening of the R3 metal liner and the failure of the locking mechanism in the R3 System to hold the R3 metal liner in place." The liner's purpose is to prevent the other hip components, including the R3 acetabular shell and its locking mechanism, from loosening. Similarly, the locking mechanism feature is supposed to ensure that the liner stays connected to the R3 acetabular shell; essentially, it assists the liner in performing the liner's function. Although plaintiffs describe these device failures as two separate defects, they are in large part describing the same phenomena—the R3 metal liner's inability to attach to the R3 acetabular shell, which resulted in plaintiffs' injuries.
>
> Because plaintiff's injuries are alleged to have been caused by the failure of multiple components, I must apply a preemption analysis for the hip replacement system as one unit, and not examine each individual component. Assuming that I did apply a preemption analysis to each individual component, I would find that plaintiff's claims with respect to the R3 metal liner, which received PMA approval, would be preempted, whereas the claims related to the R3 System, including the R3 acetabular shell and locking mechanism, would not be preempted. But, left solely with their claims with respect to the R3 System, plaintiffs would be unable to show that the R3 acetabular shell and its locking mechanism alone proximately caused plaintiffs' injuries, because plaintiffs have plead that the R3 System and the R3 metal liner together were the cause of plaintiff's injuries. Plaintiffs would have to prove that the R3 acetabular shell did not stay attached to the R3 metal liner, without being able to argue, as they have repeatedly throughout this litigation, that this failure to attach was due in large part to the R3 metal liner improperly loosening from the R3 acetabular shell. Therefore, if a claim involving the R3 metal liner's alleged defect is preempted, the entire claim should be dismissed because plaintiffs will be unable to sufficiently plead the remainder of that claim.

2014 U.S. Dist. LEXIS 35837, at *12-14. I disagree with this reasoning. In approving the BHR system with the liner from the R3 System, the FDA did not examine the R3 liner's safety and efficacy with regard to other hip replacement systems—the FDA was instead looking at whether the BHR System, as a whole, was safe and effective. It is difficult to understand why the *Bertini* court found that premarket approval of one medical device meant that claims against an entirely different medical device were preempted. While these cases from other district courts outside of

the Fourth Circuit may be cited to as persuasive authority, I do not find either of them persuasive in light of existing Supreme Court precedent and federal regulations.

Preemption is based on FDA premarket approval of a medical device, not its component parts. Supreme Court precedent speaks to whether a specific *device* underwent premarket approval or 510(k) clearance. *See generally Riegel*, 552 U.S. 312; *Lohr*, 518 U.S. 470. The relevant federal statute speaks to the approval or clearance of *devices*. *See generally* 21 U.S.C. § 360, *et seq*. The regulations interpreting the preemption provision of that federal statute discuss *devices*. *See* 21 C.F.R. 808.1. As I stated in *Lewis*, "[j]ust as a device receiving premarket approval cannot be separated into its component parts to avoid application of express preemption, a device receiving 510(k) approval cannot be separated into its component parts to create express preemption." 2014 U.S. Dist. LEXIS 4985, at *32 (internal quotation omitted). The Supreme Court and federal regulations instruct that state requirements are preempted "only when the Food and Drug Administration has established specific counterpart regulations or there are *other specific requirements applicable to a particular device*." *Riegel*, 552 U.S. at 322 (quoting 21 C.F.R. § 808.1(d) (emphasis added). The fact that the Prolene suture underwent premarket approval is irrelevant to whether the 510(k) process sets forth specific requirements applicable to the TVT-O. The law is clear that it does not.

For the reasons set forth above, Ethicon's motion for partial summary judgment based on preemption is **DENIED**.

C. Defendants' Motion for Partial Summary Judgment on Punitive Damages

Ethicon argues first that Ethicon's compliance with federal regulations precludes an award of punitive damages and second that the plaintiffs have not presented a genuine issue of material

fact with regard to punitive damages. Under Georgia law, "[p]unitive damages may be awarded only in such tort actions in which it is proven by clear and convincing evidence that the defendant's actions showed willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which would raise the presumption of conscious indifference to consequences." Ga. Code Ann. § 51-12-5.1(b). "[P]unitive damages, the purpose of which is to 'punish, penalize or deter,' are, as a general rule, improper where a defendant has adhered to [the relevant] safety regulations." *Stone Man, Inc. v. Green*, 435 S.E.2d 205, 206 (Ga. 1993). This is because "such compliance does tend to show that there is no clear and convincing evidence of wilful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which would raise the presumption of a conscious indifference to consequences." *Id.* However, regulatory compliance does not "preclude[] an award of punitive damages where, notwithstanding the compliance with applicable safety regulations, there is other evidence showing culpable behavior." *Gen. Motors Corp. v. Moseley*, 447 S.E.2d 302, 311 (Ga. 1994), *abrogated on other grounds by Webster v. Boyett*, 496 S.E.2d 459 (Ga. 1998).

As an initial matter, I do not accept Ethicon's argument that punitive damages are precluded because it complied with relevant safety regulations. As discussed above and set forth more fully in *Lewis*, the regulations with which Ethicon complied are not safety regulations. *See generally* 2014 U.S. Dist. LEXIS 4985; *see also In re: C.R. Bard, Inc. Pelvic Repair System Prods. Liabl. Litig.*, MDL No. 2187, 2013 U.S. Dist. LEXIS 78053 (S.D. W. Va. June 4, 2013) (applying Georgia law). Regardless, to survive summary judgment on their punitive damages claim, the plaintiffs must present some evidence of "willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which would raise the presumption of conscious

indifference to consequences." Ga. Code Ann. § 51-12-5.1(b). The plaintiffs in this case have not produced any evidence to support their punitive damages claim.

The plaintiffs cite to *In re: C.R. Bard, Inc. Pelvic Repair System Prods. Liabl. Litig.*, MDL No. 2187, 2013 U.S. Dist. LEXIS 78053 (S.D. W. Va. June 4, 2013), which also dealt with punitive damages under Georgia law. In that case, I rejected an argument that compliance with the 510(k) process precluded punitive damages. *See* 2013 U.S. Dist. LEXIS 78053, at *15-36. I also found that the plaintiffs had presented sufficient evidence to send the issue of punitive damages to the jury. *See id.* Specifically, the plaintiffs in *Bard* presented evidence that:

> (1) Bard had the Material Safety Data Sheet ("MSDS") which expressly prohibited the use of the material for permanent human implantation; (2) Bard concealed from the resin manufacturer that Bard was using the material for the purposes of human implantation; and that (3) Bard concealed, from a company performing a part of the polypropylene processing for Bard, that the material was being used in a medical device.

Id. at *30. The plaintiffs here have presented no such evidence. The plaintiffs argue that "Defendants knew that the design of the TVT-O was defective and likely to cause injury, but did not make adequate disclosure or warn of such danger, and further did not attempt to eliminate the known danger." (Pls.' Resp. in Opp. to Defs.' Mot. for Partial Summ. J. on Punitive Damages [Docket 111], at 14). However, they point to no specific evidence that Ethicon knew the TVT-O was defective or likely to cause injury. (*See id.*). The plaintiffs "cannot create a genuine issue of material fact through mere speculation or the building of one inference upon another." *Othentec Ltd. v. Phelan*, 526 F.3d 135, 140 (4th Cir. 2008) (internal quotation omitted). "Rather, a nonmoving party must produce some evidence (more than a 'scintilla') 'upon which a jury could properly proceed to find a verdict for the party producing it, upon whom the onus of proof is imposed.'" *Id.* (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 251 (1986)). The plaintiffs

in this case have simply not met their burden. Because the plaintiffs have not presented evidence to demonstrate that they are entitled to punitive damages, Ethicon's motion for partial summary judgment on the issue of punitive damages is **GRANTED**.

IV. Conclusion

For the reasons discussed above, Defendants' Motion for Partial Summary Judgment [Docket 83] is **GRANTED as unopposed**, Defendants' Motion for Partial Summary Judgment Based on Preemption of Certain Claims [Docket 87] is **DENIED**, and Defendants' Motion for Partial Summary Judgment on Punitive Damages [Docket 93] is **GRANTED**.

The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: July 8, 2014

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE